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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,281	07/28/2003	Michael P. Harrold	5010-036-01	4709

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EXAMINER	
SINES, BRIAN J	

ART UNIT	PAPER NUMBER
1797	

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01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,281	HARROLD, MICHAEL P.	
	Examiner	Art Unit	
	Brian J. Sines	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 23 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 23 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

Regarding claims 1 and 33, it is unclear if a single diluent or buffer is required to effect a separation of the fluid sample. For example, with the use of a purification column comprising a packed bed of ion-exchange resin, does the method require the use of different diluents, such as a binding buffer and then an elution buffer to elute the captured material of interest?

Claim Rejections - 35 USC § 102

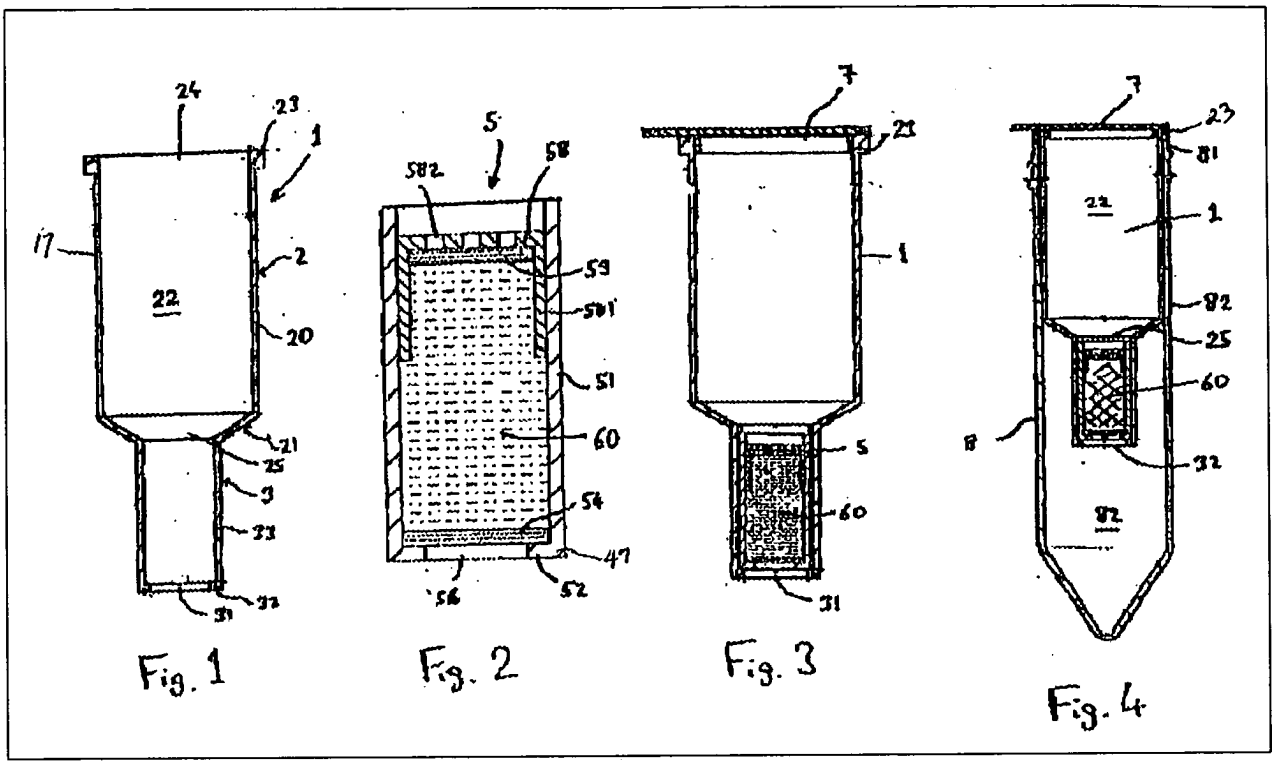
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 17, 23 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunt et al. (U.S. Pat. Appl. No. 2002/0110495) ("Hunt").

Regarding claims 1, 23 and 33, Hunt teaches a method for purifying a fluid. Hunt teaches the step of providing a microfluidic purification device, e.g., sample holder 1, having an entry port 24, a purification column, e.g., column module 5 comprising cylindrical capsule 51, comprising a purification material comprising a packed bed 60 of particulate chromatography separation medium in fluidic communication with the entry port and an output port 31, and an output reservoir inside tube 8 in fluidic communication with the purification column (see paragraphs 5 – 43 and 57 – 64; figures 1 – 4). Hunt teaches that the packed bed comprising a particulate resin can comprise various types of affinity resins for facilitating fluid sample purification (see paragraphs 65 – 87). Hunt teaches that the disclosed microfluidic device can process microliter fluid sample volumes (see paragraph 93). Hunt anticipates that the fluid sample to be processed is placed in the sample chamber 22 with a diluent or binding buffer and is driven through the column 60 into tube 8 (see, e.g., paragraphs 90 – 92 and 108). Hunt anticipates that the purification column is initially saturated with diluent or binding buffer so that the material in the fluid sample to be purified would bind with the affinity resin. It is anticipated that the purified sample after elution would be mixed with the remaining diluent flowing through the column and in the output reservoir or tube 8.



Regarding claims 2 – 9, Hunt teaches the use of various hydraulic and pneumatic means, such as gravity, pump, vacuum, and including centrifugal or centripetal, for moving diluent and fluid sample through the device (see, e.g., paragraph 94).

Regarding claims 10 and 11, Hunt teaches that the fluid sample can comprise a biological sample, such as nucleic acids or antibodies (see, e.g., paragraph 3).

Regarding claims 12 – 15, Hunt anticipates the assembling of the microfluidic device comprising the purification column comprising the purification resin material and diluent or buffer prior to use (see, e.g., paragraphs 57 - 91).

Regarding claims 16 and 17, Hunt teaches the use of size exclusion or gel filtration resin and ion exchange resin (see, e.g., paragraphs 66 and 87).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 23 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt.

Regarding claims 1, 23 and 33, Hunt teaches a method for purifying a fluid. Hunt teaches the step of providing a microfluidic purification device, e.g., sample holder 1, having an entry port 24, a purification column, e.g., column module 5 comprising cylindrical capsule 51, comprising a purification material comprising a packed bed 60 of particulate chromatography separation medium in fluidic communication with the entry port and an output port 31, and an output reservoir inside tube 8 in fluidic communication with the purification column (see paragraphs 5 – 43 and 57 – 64; figures 1 – 4). Hunt teaches that the packed bed comprising a particulate resin can comprise various types of affinity resins for facilitating fluid sample purification (see paragraphs 65 – 87). Hunt teaches that the disclosed microfluidic device can process microliter fluid sample volumes (see paragraph 93). Hunt teaches that the fluid sample to

be processed is placed in the sample chamber 22 with a diluent or binding buffer and is driven through the column 60 into tube 8 (see, e.g., paragraphs 90 – 92 and 108). Hunt teaches that the purification column is initially saturated with diluent or binding buffer so that the material in the fluid sample to be purified would bind with the affinity resin. It would have been obvious to a person of ordinary skill in the art to mix the purified sample after elution with the remaining diluent flowing through the column and in the output reservoir or tube 8 as the sample fluid flows through the device during operation.

Regarding claims 2 – 9, Hunt teaches the use of various hydraulic and pneumatic means, such as gravity, pump, vacuum, and including centrifugal or centripetal, for moving diluent and fluid sample through the device (see, e.g., paragraph 94).

Regarding claims 10 and 11, Hunt teaches that the fluid sample can comprise a biological sample, such as nucleic acids or antibodies (see, e.g., paragraph 3).

Regarding claims 12 – 15, Hunt teaches the assembling of the microfluidic device comprising the purification column comprising the purification resin material and diluent or buffer prior to use (see, e.g., paragraphs 57 - 91).

Regarding claims 16 and 17, Hunt teaches the use of size exclusion or gel filtration resin and ion exchange resin (see, e.g., paragraphs 66 and 87).

Regarding claim 18, Hunt teaches that the sample can be processed in a few minutes (see, e.g., paragraph 91). Therefore, it would have been obvious to a person of ordinary skill in the art to contact the fluid sample with the purification material for at least one minute.

Regarding claims 19 – 21, Hunt teaches that the fluid sample can comprise a biological sample, such as nucleic acids (see, e.g., paragraph 3). The use of capillary electrophoresis,

polymerase chain reaction and sequencing laboratory techniques with nucleic acids is very well known in the art. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of these techniques with a fluid sample comprising nucleic acids in order to facilitate effective sample analysis.

Regarding claim 22, the use of buffers containing chloride ions with ion exchange chromatography media is very well known in the art. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a fluid sample including chloride ions with the purification column as claimed in order to preequilibrate the column prior to use or in eluting bound sample from the column to provide a purified fluid sample.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Petithory (U.S. Pat. Appl. No. 2005/0026301) further teaches a microfluidic device comprising a purification media that can be used to purify a sample with centrifugal force (see, e.g., Abstract and paragraph 26).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Patent Examiner
Art Unit 1797